

PATENT COOPERATION TREATY

PCT

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 28 NOV 2005

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Applicant's or agent's file reference 119P/PCT2	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/US04/12200	International filing date (day/month/year) 21 April 2004 (21.04.2004)	Priority date (day/month/year) 22 April 2003 (22.04.2003)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K38/01-38/10,38/12,38/16,38/22,38/24,38/31; C07K 2/00,7/00,7/23,7/50,7/64,14/00,14/665,19/00 and US Cl.: 514/2,9,16; 530/300,311,317,321,322		
Applicant SOCIETE DE CONSEILS DE RECHES ET D'APPLICATIONS SCIENTIFIQUES, S.A.S.		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>		
Date of submission of the demand 10 November 2004 (10.11.2004)	Date of completion of this report 02 November 2005 (02.11.2005)	
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Andrew D. Kosar Telephone No. (571)272-1600	

Form PCT/IPEA/409 (cover sheet)(April 2005)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- ☒ the international application as originally filed/furnished
- ☒ the description:
pages 1-190 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____
- ☒ the claims:
pages 191-326 as originally filed/furnished
pages* NONE as amended (together with any statement) under Article 19
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____
- ☐ the drawings:
pages NONE as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

** If item 4 applies, some or all of those sheets may be marked "superseded."*

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 12 and 19-22

because:

☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for said claims Nos. 12 and 19-22

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b) and 13*ter*.2.

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/12200**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims <u>14-18</u>	YES
	Claims <u>1-11,13,23-25</u>	NO
Inventive Step (IS)	Claims <u>14-18</u>	YES
	Claims <u>1-11,13,23-25</u>	NO
Industrial Applicability (IA)	Claims <u>1-11,13-18,23-25</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and Explanations (Rule 70.7)

Claims 1-4,8,11,13, and 23-25 lack novelty under PCT Article 33(2) as being anticipated by WO/971554 A1.

WO 97/1554 A1 teaches doxorubicin, and anthracycline compounds conjugated to an LH-RH analog, a somatostatin analog, or a bombesin analog through a -C(O)-alkyl-C(O)- linker moiety and pharmaceutical compositions (claims 1-32) and a method of treating cancer (and the use of the compounds in treating tumors) via administration of said compounds (claims 33-36). [125I] labeled LH-RH conjugate is taught (Table 21-1, page 38). It is noted that the claims, as drafted, do not require the defined proviso(s), e.g., when X is doxorubicin, the proviso that at least one m or n is not 0 does not specifically require that one must choose (Doc)m or (Aepa)n as any of B1-B4.

Claims 1-4,11,13, and 23-25 lack novelty under PCT Article 33(2) as being anticipated by US 5,843,903.

US 5,843,903 teaches doxorubicin, and anthracycline compounds conjugated to an LH-RH analog, a somatostatin analog, or a bombesin analog through a -C(O)-alkyl-C(O)- linker moiety and pharmaceutical compositions (claims 1-32) and a method of treating cancer (and the use of the compounds in treating tumors) via administration of said compounds (claims 33-36). [125I] labeled LH-RH conjugate is taught (column 19, Table 21-1, accompanying description).

Claims 1-3,5,6,8 and 23 lack novelty under PCT Article 33(2) as being anticipated by FUSELIER.

Fuselier teaches camptothecin conjugates through BINAR linking groups to somatostatin analogs PENTETREOTIDE. Fuselier teaches that conjugate 2 was administered to nude mice bearing NCI-H69 transplanted small cell lung carcinomas (page 802).

Claims 1,2,5, and 7 lack novelty under PCT Article 33(2) as being anticipated by SAFAVY.

Safavy teaches PTX-Mab (Figure 1, page 304), paclitaxel conjugated through succinate to an antibody.

Claims 1,2,5,9-11, and 13 lack novelty under PCT Article 33(2) as being anticipated by HUANG.

Huang teaches paclitaxel conjugated through succinate to octreotide (Figure 4, page 456).

Claims 14-18 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the compounds that are instantly claimed.

Claims 1-11,13-18, and 23-25 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

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Box No. VII **Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

Claims 2,3 and 18 are objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof:
Claims 2 and 3 each end in two (2) periods (page 192). Claim 18 has two (2) semicolons, wherein only 1 is required (two occurrences page 210).